

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: July 14, 2015

| | | |
|------------------------------|---|--|
| * * * * * | | |
| I.H., a minor, by his mother | * | UNPUBLISHED |
| ALESKIS BROWN, | * | |
| | * | No. 13-766V |
| Petitioner, | * | |
| | * | |
| v. | * | Special Master Dorsey |
| | * | |
| SECRETARY OF HEALTH | * | Fact Ruling; Onset; Influenza (Flu) Vaccine; |
| AND HUMAN SERVICES, | * | Narcolepsy; Cataplexy |
| | * | |
| Respondent. | * | |
| | * | |
| * * * * * | | |

Michael G. McLaren, Black McLaren Jones Ryland & Griffie, P.C., Memphis, TN, for petitioner.
Darryl R. Wishard, U.S. Department of Justice, Washington, DC, for respondent.

RULING REGARDING FINDINGS OF FACT¹

I. Introduction

On October 2, 2013, Aleskis Brown (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program,² in which she alleged that her son, I.H., received an influenza (“flu”) vaccination on December 10, 2012, and which caused him to develop “narcolepsy, hypersomnia, lack of coordination/ataxia, neurologic and/or physical

¹ Because this published ruling contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, codified as amended, 44 U.S.C. § 3501 (2012). In accordance with the Vaccine Rules, each party has 14 days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

² The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act

impairments and other injuries.” Petition (“Pet.”) at 1. Because the medical records and petitioner’s testimony reference inconsistent onset dates, a fact hearing was held on April 7, 2015, to determine the onset date of I.H.’s symptoms.

Upon consideration of the record as a whole, the undersigned finds that the onset of I.H.’s injury began between January 6 and 8, 2013.

II. Procedural Background

Petitioner filed the petition for compensation on October 2, 2013. She then filed medical records from October 3, 2013, through March 14, 2014. A Statement of Completion was filed on March 14, 2014.

An initial status conference was held on November 12, 2013, during which the undersigned discussed with the parties the status of the medical record collection process. Petitioner was ordered to file the outstanding records and an updated Statement of Completion by January 13, 2014. Order dated November 12, 2013.

On April 14, 2014, respondent filed a status report stating that petitioner had not yet filed an expert report, and that upon review of I.H.’s medical records, settlement would “not be possible based upon the record as it exist[ed] at” that time. Respondent’s Status Report filed April 14, 2014, at 1.

Respondent filed the Rule 4(c) report on June 10, 2014, recommending that compensation be denied because petitioner had not offered a medical theory or a medical expert report in support of her claim. Respondent’s Rule 4(c) Report at 8. Specifically, respondent stated that petitioner had not offered a reputable medical theory establishing that the flu vaccine “either can cause narcolepsy with cataplexy, cerebellar ataxia, hypersomnia, and unspecified ‘other physical and neurological symptoms,’ (general causation), or that it did so in I.H.’s case (specific causation).” Id. Respondent further stated that while petitioner relied on a temporal relationship between the flu vaccine and the onset of I.H.’s narcolepsy, “proximity alone is insufficient to establish specific causation.” Id. Finally, respondent emphasized that the records did not establish an onset date for I.H.’s alleged vaccine-related injuries because the records listed various and inconsistent onset dates. Id.

On August 5, 2014, the undersigned held a status conference to discuss the conflicting information in the record regarding the onset date of I.H.’s injuries. The undersigned suggested that petitioner further investigate whether there were any additional records that would assist in clarifying the onset date. Order dated August 5, 2014, at 1-2. Petitioner filed a status report on October 6, 2014, stating that she did “not have any additional records to file” at that time. Petitioner’s Status Report filed October 6, 2014. On October 28, 2014, respondent filed a status report identifying the records that contained inconsistent dates regarding onset. Respondent’s Status Report filed October 28, 2014, at 1-2.

On April 7, 2015, a fact hearing was held in Memphis, Tennessee, to obtain testimony from petitioner to help determine the onset date of I.H.’s alleged injuries. After the hearing, the

undersigned ordered the parties to file the photographs and additional medical records referenced during the hearing by May 15, 2015. Order dated April 15, 2015. This case is now ripe for adjudication on the issue of onset.

III. Standards for Finding Facts

Special masters must first analyze medical records when beginning the fact finding process. 42 U.S.C. § 300aa-11(c)(2). Special masters may rely on medical records and testimony when determining the onset date of an alleged vaccine-related injury. See Cucuras v. Sec’y of Health & Human Servs., 993 F.2d 1525, 1526 (Fed. Cir. 1993). Contemporaneous medical records are presumed to be accurate. Id. at 1528.

When medical records and affidavits contain discrepancies or contradictions, special masters are encouraged to hold hearings to obtain testimony from the affiants. See Campbell v. Sec’y of Health & Human Servs., 69 Fed. Cl. 775, 779-80 (2006). “Medical records, in general, warrant consideration as trustworthy evidence,” and in the face of conflicting oral testimony and contemporaneous medical records, special masters may give greater weight to contemporaneous medical records. Cucuras, 993 F.2d at 1526, 1528. Special masters may also consider explanations for inconsistencies between medical records and testimony. For example, inconsistencies can result from: (1) a person’s failure to tell doctors all relevant details; (2) a doctor’s failure to document everything reported to him or her; (3) a person’s failure to recall events when testifying; and/or (4) a person’s purposeful recounting of nonexistent symptoms. See La Londe v. Sec’y of Health & Human Servs., 110 Fed. Cl. 184, 203 (2013). The strength of a witness’s testimony determines whether the testimony is more probative than medical records. See Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); see also Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

IV. Summary of the Evidence

The undersigned has considered the entirety of the record. § 300aa-13(a)(1). The evidence presented includes: I.H.’s medical records, petitioner’s affidavit, and petitioner’s testimony. A review and analysis of each type of evidence is discussed below.

A. Medical Records

I.H. was born on August 19, 2005, and he received the flu vaccine at issue in this case on December 10, 2012. Petitioner’s Exhibit (“Pet. Ex.”) 2 at 1. The first time I.H. saw a physician after his December 2012 flu vaccination was on February 15, 2013, when he presented to Dr. Abubakar Naida’s office for a well-child visit. Pet. Ex. 4 at 1. The records from this visit state that I.H. did not have any sleep problems and note that he was sleeping eight to nine hours a night and napping for two hours during the day. Id. The records also state that petitioner did not report any problems to the nurse who evaluated I.H. Id.

On March 4, 2013, petitioner took I.H. to the emergency room (“E.R.”) at Le Bonheur Children’s Hospital (“Le Bonheur”) for general weakness and fatigue. Pet. Ex. 7 at 251, 264.

The chief complaint was “fatigue times one month” (approximately February 4, 2013). Id. at 264. I.H.’s diagnosis on that date was fatigue. Id. at 265.

Two days later, on March 6, 2013, petitioner brought I.H. back to Dr. Naida’s office because I.H.’s school contacted petitioner to inform her that I.H. had been falling asleep during the school day. Pet. Ex. 4 at 5; Pet. Ex. 7 at 13. The medical records from this visit state that petitioner told Dr. Naida that I.H.’s symptoms started two months prior (approximately January 6, 2013). Pet. Ex. 12 at 22. Dr. Naida documented that I.H. was slightly ataxic and wobbly when walking. Pet. Ex. 4 at 5. Dr. Naida instructed petitioner to take her son to the E.R. at Le Bonheur because he thought I.H. could have post viral cerebellar ataxia or intoxic encephalopathy. Id. at 6.

The medical records from the March 6, 2013 visit to Le Bonheur list three different onset dates. Dr. Shelley Ost, one of I.H.’s attending physicians, reported that I.H. “presents 1-1/2-month history of fatigue” (one month is approximately February 6; one and a half months is approximately January 20, 2013; two months is approximately January 6, 2013). Pet. Ex. 7 at 29. I.H.’s neurology report stated that he had a “month-long history of being overly sleepy” (approximately February 6, 2013). Id. at 36. Dr. Mary McGinty noted that I.H.’s “fatigue and sleepiness started about 6 weeks ago” (approximately January 23, 2013). Id. at 39.

During this March 6, 2013 visit, the attending physicians noted that I.H. was experiencing weakness and fatigue. Pet. Ex. 7 at 30. Petitioner told the physicians that she had been monitoring I.H.’s sleep habits to ensure that he was not waking up during the night to play video games. Id. at 29. During this E.R. visit, I.H. fell asleep in the middle of having conversations and when he attempted to complete tasks. Id. at 13.

On March 7, 2013, petitioner took I.H. for a consultation with a neurologist, Dr. Paras Bhattarai, at Le Bonheur. Pet. Ex. 7 at 22. The record from this visit indicates that I.H. was experiencing hallucinations before falling asleep. Id. Upon examination, I.H. was slightly unsteady when he walked. Id. Dr. Bhattarai concluded that I.H. suffered from excessive daytime sleepiness and possible narcolepsy.³ Id. at 24. He suggested that I.H. undergo sleep studies. Id.

The March 7, 2013 medical records list three different onset dates for I.H.’s symptoms. Dr. Bhattarai noted, “Mother says that 1/2 month ago, the patient started to have sleepiness during the daytime” (one half month or two weeks prior is approximately February 21, 2013; one month prior is approximately February 7, 2013; and two months prior is approximately January 7, 2013). Another record from that date states that I.H. had a “history of excessive daytime sleepiness for 2-3 weeks” (from approximately February 14, 2013 to February 23, 2013). Id. at 24. Dr. Shelley Ost’s progress note from March 7, 2013, states that I.H. had “6weeks [sic] of sleepiness” (approximately January 24, 2013). Id. at 53.

³ Narcolepsy is a “recurrent, uncontrollable, brief episodes of sleep, often associated . . . hallucinations, cataplexy, and sleep paralysis. Dorland’s Illustrated Medical Dictionary 1232 (32nd ed. 2012) (“Dorland’s”).

On March 8, 2013, petitioner took I.H. to meet with pulmonologist and sleep medicine specialist, Dr. Robert Schoumacher. Pet. Ex. 7 at 19, 21. The notes from this visit state “[p]er mom, [I.H.] began to have daytime sleepiness about 2 months” (approximately January 8, 2013). Id. at 19. During this visit, Dr. Schoumacher noted that I.H.’s history was “suspicious for narcolepsy.” Id. at 20. The medical records note that petitioner stated that I.H. had fallen asleep during a professional basketball game that they had recently attended and also at the circus. Id. at 19.

Later that same day, Dr. Bhattarai met with I.H. and petitioner. Pet. Ex. 7 at 46. Dr. Bhattarai’s progress note states that I.H. had “excessive sleepiness for more than 1 month” (approximately February 8, 2013). Id. at 47. On that same date, medical student Patrick Cleeton’s progress note stated that I.H. had a “6 wk h/o excessive sleepiness” (approximately January 25, 2013). Id. at 50, 52. I.H.’s Le Bonheur discharge papers, dated March 8, 2013, state that petitioner reported that I.H.’s narcolepsy symptoms began 7 weeks prior (approximately January 18, 2013). Pet. Ex. 3 at 1; Pet. Ex. 7 at 26.

On March 12 and 13, 2013, I.H. underwent sleep studies with Dr. Schoumacher. Pet. Ex. 5 at 1-3. Dr. Schoumacher diagnosed I.H. with narcolepsy and cataplexy.⁴ Id. at 3. The sleep study assessment by Dr. Schoumacher notes that I.H. “was recently hospitalized for complaints of severe daytime sleepiness of 2 months duration” (approximately January 12-13, 2013). Pet. Ex. 9 at 14.

During a March 19, 2013 follow-up visit with Dr. Schoumacher, petitioner stated that I.H.’s condition had “worsened over the past year.” Pet. Ex. 9 at 11. The notes from that visit also state that I.H. has had a “2month [sic] history of poor sleep,” consistent with the dated listed in Dr. Schoumacher’s first visit records. Id. Dr. Schoumacher confirmed the assessment of narcolepsy and cataplexy. Id. at 13.

On March 22, 2013, I.H. followed up with pediatric pulmonologist Dr. James Tutor. Pet. Ex. 9 at 9-10. During this visit, petitioner reported that I.H. was hallucinating, had to take naps at school, and suffered from cataplexy. Id. at 9. Petitioner also requested that I.H. receive a prescription for Adderall. Id. Dr. Tutor’s assessment was narcolepsy with cataplexy. Id. at 10.

On April 9, 2013, I.H. again followed up with Dr. Schoumacher. Pet. Ex. 9 at 7-8. At this point, I.H.’s sleep had improved, and he woke up on fewer occasions during the night, but his mother noted that his daily functions worsened if he did not take naps at school. Id. at 7.

On April 11, 2013, and August 26, 2013, petitioner met with a committee from I.H.’s school to develop a service plan for I.H. based on the Rehabilitation Act of 1973. Pet. Ex. 11 at 7; Pet. Ex. 35 at 10. To make sure I.H. did not experience losses of energy, the school agreed to give I.H. snacks if he experienced sweating or faintness. Pet. Ex. 11 at 7.

⁴ Cataplexy is “a condition in which there are abrupt attacks of muscular weakness and hypotonia triggered by an emotional stimulus . . . It is often associated with narcolepsy.” Dorland’s at 303.

On June 4, 2013, petitioner took I.H. to Dr. Schoumacher for a follow-up visit. Pet. Ex. 9 at 5-6. At that time, I.H.'s sleep schedule and quality of sleep had improved, although he continued to wake up at night and take naps throughout the day. Id. at 5. I.H. continued to be assessed with severe narcolepsy with cataplexy. Id. at 6. On July 30, 2013, I.H. again followed up with Dr. Schoumacher, who noted that I.H.'s sleep had improved. Id. at 3-4.

On August 22, 2013, I.H. presented to Dr. Douglas MacGaw of the Raleigh Group, P.C., with complaints of fatigue and sweating after standing for a short period of time. Pet. Ex. 6 at 10, 12. During this visit, petitioner reported that I.H. had narcolepsy, but Dr. Douglas MacGaw noted that I.H. had a normal exam and there was "no evidence of disease." Id.

On September 24, 2013, I.H. returned to see Dr. Schoumacher. Pet. Ex. 9 at 1. I.H.'s sleep quality and schedule continued to improve, and he was doing better at school, but he continued to suffer from sleep paralysis, cataplexy, and nightmares. Id. The assessment again was severe narcolepsy with cataplexy. Pet. Ex. 9 at 2.

On October 28 and 29, 2013, I.H. met with child psychologist, Dr. Peter Zinkus. Pet. Ex. 8 at 1. It was noted that I.H. continued to suffer from sleep paralysis and hallucinations, and Dr. Zinkus thought I.H. might also have adjustment disorder.⁵ Id. at 1-4.

B. Petition, Affidavit, and Testimony

1. Petition and Affidavit

The petition and petitioner's affidavit allege that after I.H. received the flu vaccine on December 10, 2012, he developed excessive sleepiness beginning in mid-January 2013 (approximately five to seven weeks after receiving the flu vaccine). Pet. Ex. 1 at 1; Pet. at 1-2. This suggests an onset timeframe of January 14 through January 28, 2013. Petitioner stated in her affidavit that I.H.'s symptoms were not present before he received the flu vaccination and that they persisted for at least six months thereafter. Pet. Ex. 1 at 2.

2. Testimony

During the fact-finding hearing held on April 7, 2015, petitioner was unable to pinpoint the date on which I.H.'s symptoms began. Petitioner admitted that when she provided I.H.'s doctors with onset dates, she just "threw [out] those times" and did not realize she would have to account for specific days. Tr. 42. Petitioner testified that she "really didn't have a specific time" in mind because she did not know at the time of I.H.'s medical appointments that his condition was serious. Tr. 42. Petitioner did note that I.H.'s symptoms became progressively worse. Tr. 73. Ultimately, petitioner stated that I.H.'s onset "... started within [the January 6, 2013] time period ..." and not in February 2013 (agreeing with counsel that onset was on January 6, 2013). Tr. 43.

⁵ Adjustment disorder is "a maladaptive reaction to identifiable stressful life events" Dorland's at 547.

Petitioner did recall three events that helped her to specify the onset date. First, petitioner recalled that she was aware of I.H.'s unusual lethargy when she observed a photo taken of him on Christmas day, December 25, 2012. Tr. 83. Petitioner testified that I.H. looked "exhausted" in this Christmas photograph. Id. Though petitioner submitted this picture and others, the photographs were not dated or date stamped. Pet. Ex. 61 at 17. Shortly after Christmas, during the December-January 2012-2013 school holiday break, I.H.'s grandmother cared for I.H. while petitioner worked, but petitioner did not recall the grandmother stating that I.H. was notably tired while in her care. Tr. 86.

Second, petitioner testified that on January 23, 2013, she brought I.H. to a professional basketball game between the Grizzlies and the Lakers in an attempt to get her son "more involved," because she thought that her son's lethargy could be the result of being involved in too few activities. Tr. 71-72. According to petitioner, I.H. fell asleep within 20 minutes of arriving at the basketball game. Tr. 71. When the undersigned asked petitioner to estimate how long before the date of the basketball game I.H. had been unusually sleepy, petitioner stated that it had been at least "three weeks or so" (approximately January 2, 2013). Tr. 83.

Finally, petitioner testified that on February 23, 2013, she brought I.H. to the Shrine Circus. Tr. 45, 91. The circus "was another [of petitioner's] attempt[s] . . . like the basketball game . . ." to get I.H. more involved in outside activities, but I.H. fell asleep during the circus. Tr. 70-71.

Additionally, petitioner attempted to clarify some of the medical record notations regarding the onset date of I.H.'s symptoms. Petitioner confirmed that she brought I.H. to Dr. Naida's office on February 15, 2013. Tr. 31. However, while the medical records from that visit indicate that the visit was a well-child visit, petitioner insisted that she brought I.H. to Dr. Naida that day to "ask [the doctor] about [I.H.'s] sleeping habits." Tr. 31; Pet. Ex. 12 at 18. Petitioner said that the reason the nurse made a note of I.H.'s nighttime and daytime sleep habits during this visit was because I.H. had started sleeping "way more" than usual. Tr. 33. Petitioner also stated that she began giving I.H. multivitamins to address his sleepiness. Tr. 32.

Regarding the medical records from I.H.'s March 19, 2013 visit with Dr. Schoumacher, which state that I.H.'s condition had worsened over the past year, petitioner testified she meant that I.H. had not had any symptoms before January 2013. Tr. 57.

Petitioner testified that while some of the medical records indicate that I.H. exhibited narcolepsy symptoms for one month, she told the doctors that his symptoms had occurred for "at least a month." Tr. 36. Petitioner also clarified that the doctors' notations of "1/2" months meant one to two months, not a half month, because that is how petitioner states she would have characterized the duration of I.H.'s symptoms. Tr. 44.

While the medical records from I.H.'s visit with Dr. Naida on March 6, 2013, indicate that petitioner brought I.H. to the doctor that day because the school had contacted petitioner to tell her that I.H. had been falling asleep, petitioner testified that she was the one that contacted the school to notify them that she was taking I.H. out of school to follow up with Dr. Naida. Tr. 40.

V. Evaluation of the Evidence

Based on an evaluation of the evidence as a whole, the undersigned finds that I.H.'s symptoms began between January 6 and 8, 2013, and progressively worsened thereafter. I.H.'s medical records and petitioner's testimony and affidavit are not necessarily contradictory, given the insidious nature of the onset of I.H.'s illness. But as petitioner testified, she did not realize that her son was ill until his fatigue and sleepiness persisted for some time, and then it was difficult for her to accurately recall when the first symptoms began. Petitioner's affidavit, testimony, the petition, and a number of the medical records support the undersigned's finding that the onset date was early-to-mid January 2013.

Dr. Schoumacher, the sleep specialist who diagnosed I.H. with narcolepsy and cataplexy, first recorded that I.H.'s symptoms began two months prior to I.H.'s first visit with him on March 8, 2013. Pet. Ex. 7 at 19. This places the onset date at January 8, 2013. Again, on March 12 and 19, 2013, Dr. Schoumacher noted that I.H. had recently been assessed with a two month history of symptoms. Pet. Ex. 9 at 14; Pet. Ex. 9 at 11. Thus, Dr. Schoumacher consistently documented an onset date of I.H.'s symptoms as January 8, 2013. Similarly, Dr. Naida, I.H.'s primary care physician, recorded that I.H.'s symptoms began on January 6, 2013. Pet. Ex. 12 at 22 (noting that I.H.'s symptoms started two months prior to I.H.'s visit with Dr. Naida on March 6, 2013). While the medical records set forth a number of potential onset dates, I.H.'s primary care physician, Dr. Naida, and his sleep specialist, Dr. Schoumacher, both documented a two month duration of symptoms, which puts the onset of symptoms occurring from January 6-8, 2013. Presumably, Dr. Schoumacher, due to his expertise on sleep disorders, was careful to take and document an accurate history. Dr. Naida, as the child's treating pediatrician, knew the child and his mother, and his history is also presumed to be reliable.

Petitioner's testimony also supports Dr. Schoumacher and Dr. Naida's onset dates as between January 6 and 8, 2013. Petitioner testified that she brought I.H. to the professional basketball game on January 23, 2013. Petitioner testified that she recalled that I.H. had shown symptoms of daytime sleepiness approximately three weeks prior to this event, placing the onset date in early January 2013, consistent with the history taken by Dr. Schoumacher and Dr. Naida. Tr. 83.

Accordingly, the undersigned finds that the onset of I.H.'s injury began between January 6 and January 8, 2013.

VI. Conclusion

The undersigned finds that the onset date of I.H.'s injuries began between January 6 and January 8, 2013. The respondent is ORDERED to file a status report by **Friday, August 14, 2015**, stating how she would like to proceed.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master